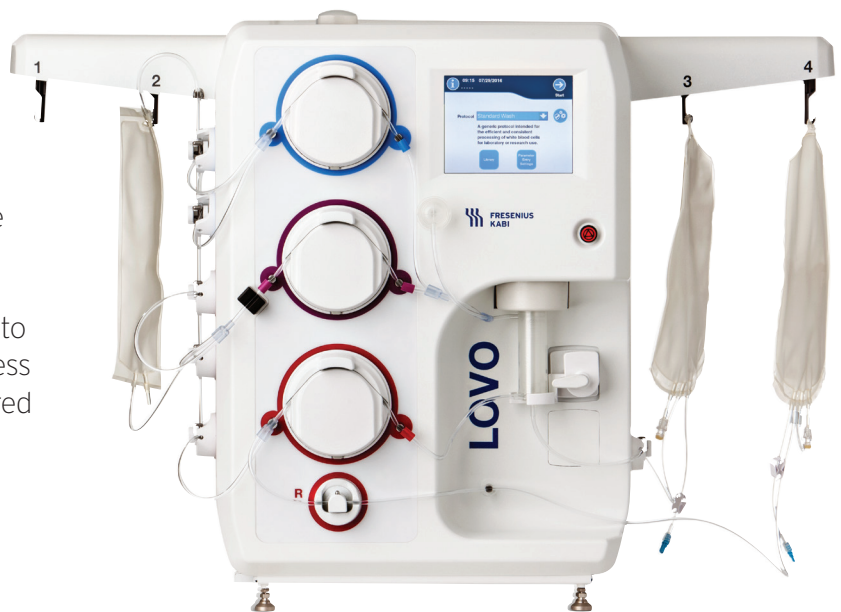


DXT for use with the LOVO instrument

The Partnership of Data & Compliance

What is DXT?

- A software application designed to receive, store and transmit procedure information
- Information is transferred from Lovo to the DXT software via a wired or wireless connection and can then be transferred to your external systems
- Supports 21 CFR Part 11 compliance



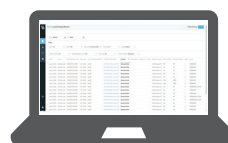
Electronically transfer procedure record data | Anytime, Anywhere Access



Lovo



DXT



End User

DXT for use with the LOVO instrument

Seamlessly view and store electronic data

Procedure Report - Lovo			
Times (hh:mm:ss)		Volumes (mL)	
Estimated Total	Measured	Estimated Total	Measured
Source Processing 01:17:02	01:47:40	304	314
Duration	00:43:11	ACK buffer	200*
	Automated	Final Product/Retentate (mL)	2386
	Paused	Filterate (mL)	2382
	00:00:00	Target Minimum Final Product Volume	No
Supernatant Removal			
% Washout	Estimated Total		
Residual (mL)	99.9725		
	0.13		
Incubation			
Estimated Duration (HH:MM:SS)	Cycle 1->2	Estimated Duration (HH:MM:SS)	00:03:00
Measured Automated Duration (HH:MM:SS)	00:03:00	Measured Automated Duration (HH:MM:SS)	00:03:00
Measured Total Duration (HH:MM:SS)	00:03:00	Measured Total Duration (HH:MM:SS)	00:03:00
Estimated Volume (mL)	400*	Estimated Volume (mL)	400*
Measured Volume (mL)	408	Measured Volume (mL)	408
Theoretical Retentate Composition			
Cells	Percentage (%)		
Supernatant	100		
Solution 1	0.1		
Solution 2	0.1		
Total	100		
PROCEDURE PARAMETERS			
General Parameters			
Spinner Idle Rate (RPM)	600	Source Rinse Volume (mL)	40
Final Product Media Susp. Rate (mL/min)	100	Pause After Source Rinse	Enabled
High Pressure Limit (mmHg)	500	Pause After Source Rinse Text	Mix Source
Low Pressure Limit (mmHg)	30	IP Top Port Rinse Volume (mL)	20
Disposable Kit Prime Solution	Solution 1	IP Bottom Port Rinse Volume (mL)	10
		Final IP Bottom Port Rinse Volume (mL)	10
Source Prime Parameters			
Volume (mL)	Prime 1	Prime 2	Prime 3
Flow Rate (mL/min)	100		
Pause After Prime	Disabled		
Pause After Prime Text			
Container Information			
Source	Type	Location	Cap. (mL)
Final Filterate	Original*	On-Scale*	1000*
Retentate	Original*	On-Scale*	800*
Procedure Record Key			
2021032312429_WJC12345_PRR	Fresenius Kabi	Printed On:	Page:
Location		10/27/2021 12:07:52 PM	2 of 6

Supports 21 CFR Part 11 compliance

Access Procedure Data, Anywhere, Anytime.

What is included?

- Non-editable Procedure reports documenting programmed parameters, procedure results, calibration and events times (exportable to PDF or Excel)
- Procedure listings providing a historical view of procedures from all devices (exportable to Excel)

PROCEDURE NOTES				
User ID	Date / Time	Description		
PROCEDURE EVENTS				
User ID	Date / Time	Name	Type***	Alert
User 1	4/13/2021 11:12 AM	Kit Install Complete	0	
User 1	4/13/2021 11:12 AM	Changed User ID->mkm	2	
User 1	4/13/2021 11:13 AM	Alert 2016 Unable to Pressurize Kit 5 6	1	Code 2016 Class ALERT Data 1 5 Data 2 6

DXT System Requirements

Operating System	Windows 10 Professional	Windows Server 2019
Database Management System (DBMS)	SQL Server 2017 Express	SQL Server 2017
Processor	2 cores @ 2.3 GHz	4 cores @ 2.3 GHz
Memory	8 GB	8 GB
Disk Size*	500 GB SSD	500 GB SSD

* The disk size requirements will depend on organizational data retention policy for data immediately accessible through DXT.

Additional System Features

- Lovo communicates wirelessly or wired
- LIMS interface compatible
- Support provided by Fresenius Kabi team

Refer to the LOVO Cell Processing System Operator's Manual, DXT Administrator's Guide and DXT User's Guide for a complete list of warnings and precautions associated with the use of these products.

The LOVO Cell Processing system is for laboratory use only. Unless the user has obtained advance clearance or approval from the appropriate regulatory agency, cells processed on this system are not intended for diagnostic purposes, direct transfusion, or for use in the production of therapeutic products or vaccines for clinical use. For applications requiring regulatory clearance or approval, users may request the required LOVO technical documentation from Fresenius Kabi to support their submissions.

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